

Clinical Trial Protocol

Iranian Registry of Clinical Trials

16 Sep 2026

In vivo bioequivalence study of Azithromycin 250 mg capsule manufactured by Ani Darman Co. compared with Zithromax®

Protocol summary

Study aim

Investigating the bioequivalence of Azithromycin 250 mg capsule compared to innovator product

Design

Twenty-four healthy male volunteers will participate in the study randomly as two groups of twelve people. Each volunteer will receive a single dose of drug in two periods. In one period the test formulation and in another period the reference formulation will be received.

Therefore, each volunteer will be his own "Control".

Settings and conduct

After administration of single dose of each formulation, the blood samples will be taken in predetermined time intervals up to 72 hours. The samples will be stored in freezer -4 degrees centigrade until analysis and sample quantitation.

Participants/Inclusion and exclusion criteria

General Health (in terms of Liver, Heart and Kidney), Age (18-59 years old)

Intervention groups

Test group: Receiving the test product
Control group: Receiving the innovator product

Main outcome variables

Plasma concentration of drug

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20210519051345N13**

Registration date: **2022-08-15, 1401/05/24**

Registration timing: **prospective**

Last update: **2022-08-15, 1401/05/24**

Update count: **0**

Registration date

2022-08-15, 1401/05/24

Registrant information

Name

Parvin Zakeri-Milani

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 41 3334 8801

Email address

pzakeri@tbzmed.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-09-11, 1401/06/20

Expected recruitment end date

2023-03-11, 1401/12/20

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

In vivo bioequivalence study of Azithromycin 250 mg capsule manufactured by Ani Darman Co. compared with Zithromax®

Public title

Investigating the in vivo bioequivalence of Azithromycin 250 mg capsule

Purpose

Other

Inclusion/Exclusion criteria

Inclusion criteria:

General Health (in terms of Liver, Heart and Kidney)

Exclusion criteria:

Smoking, History of cardiovascular disease, liver disease and kidney disease, Pregnancy, Alcohol and drug

addiction, History of drug allergy

Age
From **18 years** old to **59 years** old

Gender
Both

Phase
Bioequivalence

Groups that have been masked
No information

Sample size
Target sample size: **24**

Randomization (investigator's opinion)
Randomized

Randomization description
To randomly assign participants in two groups, 24 cards with numbers 1 to 24 will be used in closed envelopes that are arranged irregularly. Each candidate will pick up an envelope. Numbers 1-12 will be placed in group A and numbers 13-24 will be placed in group B. Group A will receive intervention 1 (test product) and group B will receive intervention 2 (innovator product), and after the first period, the interventions of both groups will change for the second period.

Blinding (investigator's opinion)
Not blinded

Blinding description
Placebo
Not used

Assignment
Crossover

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Biomedical Research Committee, Tabriz University of Medical Sciences

Street address
No.2 Central Building 3rd Floor, University of Medical Sciences, Daneshgah st.

City
Tabriz

Province
East Azarbaijan

Postal code
51664-14766

Approval date
2022-08-01, 1401/05/10

Ethics committee reference number
IR.TBZMED.REC.1401.403

Health conditions studied

1

Description of health condition studied
In the present study, in vivo bioequivalence of Azithromycin 250 mg capsules (Ani Darman Co.) compared to Zithromax®

ICD-10 code
ICD-10 code description

Primary outcomes

1

Description
Plasma concentration of drug

Timepoint
0.5-72 hours in predetermined time intervals after drug administration

Method of measurement
HPLC (High performance liquid chromatography)

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: Intervention group will receive a single test drug product. Blood samples will be collected for 72 hours at the mentioned times after drug administration and the concentration of drug in blood samples will be measured by liquid chromatography equipped with mass spectroscopy detector

Category
Treatment - Drugs

2

Description
Control group: Control group will receive one reference drug product. Blood samples will be taken from the volunteers for 72 hours at the mentioned times after drug administration and the concentration of drug in blood samples will be measured by liquid chromatography with mass spectroscopy detector

Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Faculty of Pharmacy, Tabriz University of Medical Sciences

Full name of responsible person
Parvin Zakeri-Milani

Street address

Faculty of Pharmacy, University of Medical Sciences,
Golgashst st., Attar Neishaboori st.

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Phone

+98 41 3334 8801

Email

pzakeri@tbzmed.ac.ir

Sponsors / Funding sources

1

Sponsor**Name of organization / entity**

Tabriz University of Medical Sciences

Full name of responsible person

Parviz Shahabi

Street address

No.2 Central Building 3rd Floor, University of Medical
Sciences, Daneshgah st.

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shahabip@tbzmed.ac.ir

Grant name**Grant code / Reference number****Is the source of funding the same sponsor
organization/entity?**

No

Title of funding source

Ani Darman Pharmaceutical Company

Proportion provided by this source

100

Public or private sector

Private

Domestic or foreign origin

Domestic

Category of foreign source of funding

empty

Country of origin**Type of organization providing the funding**

Industry

Person responsible for general inquiries

Contact**Name of organization / entity**

Tabriz University of Medical Sciences

Full name of responsible person

Parvin Zakeri-Milani

Position

Professor

Latest degree

Ph.D.

Other areas of specialty/work

Medical Pharmacy

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Faculty of Pharmacy, University of Medical Sciences,
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Person responsible for scientific inquiries

Contact**Name of organization / entity**

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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Undecided - It is not yet known if there will be a plan to

make this available

Study Protocol

Undecided - It is not yet known if there will be a plan to
make this available

Statistical Analysis Plan

Undecided - It is not yet known if there will be a plan to
make this available

Informed Consent Form

Undecided - It is not yet known if there will be a plan to
make this available

Clinical Study Report

Undecided - It is not yet known if there will be a plan to
make this available

Analytic Code

Not applicable

Data Dictionary

Not applicable